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## Original article

# Acupuncture in fibromyalgia: a randomized, controlled study addressing the immediate pain response



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## ABSTRACT

**Objective:** To evaluate the efficacy of acupuncture in the treatment of fibromyalgia, considering the immediate response of the visual analogue pain scale (VAS) as its primary outcome. **Methods:** Randomized, controlled, double-blind study including 36 patients with fibromyalgia (ACR 1990) selected from the outpatient rheumatology clinic, Santa Casa de Misericórdia, Ponta Grossa, PR. Twenty-one patients underwent an acupuncture session, under the principles of the traditional Chinese medicine, and 15 patients underwent a placebo procedure (sham acupuncture). For pain assessment, the subjects completed a Visual Analogue Scale (VAS) before and immediately after the proposed procedure. The mean change in VAS was compared among groups.

**Results:** The variation between the final and initial VAS values was  $-4.36 \pm 3.23$  ( $P = 0.0001$ ) in the treatment group and  $-1.70 \pm 1.55$  in the control group ( $P = 0.06$ ). The difference in terms of amplitude of variation of VAS (initial – final VAS) among groups favored the actual procedure ( $P = 0.005$ ). The effect size (ES) for the treatment group was  $d = 1.7$ , which is considered a large effect. Although small, the statistical power of the sample for these results was very relevant (94.8%).

**Conclusion:** Acupuncture has proven effective in the immediate pain reduction in patients with fibromyalgia, with a quite significant effect size.

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## Acupuntura na fibromialgia: um estudo randomizado-controlado abordando a resposta imediata da dor

### R E S U M O

#### Palavras-chave:

Acupuntura  
Fibromialgia  
EVA  
Dor crônica

**Objetivo:** Avaliar a eficácia da acupuntura no tratamento da fibromialgia, considerando-se como desfecho primário a resposta imediata da escala visual analógica (VAS) para avaliação da dor.

**Material e métodos:** Estudo randomizado, controlado e duplo-cego incluindo 36 pacientes portadores de fibromialgia (ACR 1990) selecionados no ambulatório de Reumatologia da Santa Casa de Misericórdia de Ponta Grossa, PR. Vinte e um pacientes foram submetidos a uma sessão de acupuntura, nos moldes da Medicina Tradicional Chinesa, e 15 pacientes foram submetidos a um procedimento placebo (acupuntura *sham*). Para avaliação da dor, os indivíduos preencheram uma Escala Visual Analógica (VAS) antes e imediatamente após o procedimento proposto. As médias na variação da VAS foram comparadas entre os grupos. **Resultados:** A variação entre o valor da EVA final e da EVA inicial foi de  $-4,36 \pm 3,23$  ( $P=0,0001$ ) no grupo de tratamento e de  $-1,70 \pm 1,55$  no grupo de controle ( $P=0,06$ ). A diferença na amplitude de variação da EVA (EVA inicial – final) entre os grupos favoreceu o procedimento verdadeiro ( $P=0,005$ ). O tamanho de efeito (*effect size* – ES) para o grupo de tratamento foi de  $d=1,7$ , o que é considerado um efeito grande. Embora com uma amostra reduzida, seu poder estatístico para esses resultados foi bastante relevante (94,8%).

**Conclusão:** A acupuntura mostrou ser eficaz na redução imediata da dor em pacientes portadores de fibromialgia, com um tamanho de efeito (*effect size*) bastante significativo.

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## Introduction

Fibromyalgia is a non-inflammatory syndrome manifested primarily on the musculoskeletal system by a chronic widespread pain, often associated with other symptoms such as fatigue, sleep disturbance and mood disorders.<sup>1-3</sup> The pain usually exacerbates after physical activity and there are patients who complain of its intensification when exposed to cold and humidity.<sup>3</sup>

The etiology of fibromyalgia remains unknown, being considered by some authors as a somatisation syndrome.<sup>4</sup> But, mostly from the 1980s on, this condition came to be understood as a chronic pain syndrome in which the sensitization of the central nervous system (CNS) to pain plays a major role. Its diagnostic criteria have been defined by the American College of Rheumatology in 1990, and in 1992 the World Health Organization (WHO) recognized fibromyalgia as a disease.<sup>4</sup>

The available treatments for this disease are only partially effective and focus on the relief of symptoms; and its cure, like other rheumatic diseases, constitutes a still elusive task.<sup>5,6</sup> Acupuncture has been applied as a therapeutic modality in a wide variety of painful conditions.<sup>7</sup> Its neurobiological effects, that interfere on neurotransmitters related to pain and depression, qualify this as a proper technique for the treatment of chronic pain.<sup>7,8</sup>

In this study, we sought to evaluate the efficacy of acupuncture in treating fibromyalgia, considering the immediate response of the visual analogue scale of pain as the primary outcome.

## Material and methods

### Patients and controls

Thirty-six patients with fibromyalgia diagnosed according to the 1990 American College of Rheumatology classification criteria seen at the outpatient rheumatology clinic at the Hospital Santa Casa de Misericórdia, Ponta Grossa (University Hospital, UEPG) were selected. Volunteers selected for the study were randomly distributed into two groups. Patients with contraindication to acupuncture, for instance, individuals with needle phobia, bleeding diathesis, pregnant or lactating women, were excluded.

The sample size calculation was performed by estimating a Cohen's *d* coefficient = 1.2 (effect size) for an  $\alpha$ -error of 5% and a sample power of 80%, and we inferred that the required sample size was at least 12 patients in each group.

The randomization followed a computer generated table of random numbers by Research Randomizer ([www.randomizer.org](http://www.randomizer.org)). The study was approved by the Universidade Estadual de Ponta Grossa (UEPG) Ethics Committee on Human Research (COEP) and all individuals involved signed an informed consent form.

Table 1 shows the baseline characteristics of the selected patients. There was no statistically significant difference between the two groups.

### Intervention

The acupuncture methods applied were identically standardized and implemented in all subjects studied, according to

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